

system, including FRED. Therefore, any individual conducting FDA-regulated activities should complete the training program. This training, and documentation of this training, is also required by 21 Code of Federal Regulations (CFR), Part 11, and the associated predicate rules.

A CD-ROM with this training is available for all USAMRMC personnel. To receive a copy of this training program, send requests via email to USAMRMC.MeRITS@amedd.army.mil with contact information.

Once the Course 100 Series Training Program is successfully completed, end users must then attend FRED End User Training. The purpose of this training is to provide end users with the necessary skills to perform basic functions within FRED. These functions include, but are not limited to, logging into FRED, searching for information, as well as viewing and downloading documents that have been loaded into FRED by each organization's Knowledge Manager (KM). KMs provide front-line support to the Command's end user community, and their responsibilities include regulated information and document control management; systems operations; as well as end user support and training. As a final activity for FRED End User Training, all attendees will be issued a username and password.

To request FRED End User Training, or if there are additional questions or concerns, send an email to USAMRMC.MeRITS@amedd.army.mil.

Important Contacts

EDMS Project Leader:

USAMRMC.MeRITS.EDMS@amedd.army.mil

Your Organization's Knowledge Manager:

Phone/Email:

URLs:

FRED-TR (Training)

<https://fred-tr.armymerits.org/>

FRED (Production)

<https://fred.armymerits.org/>



Protect, Project, Sustain

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MeRITS PMO EDMS



General Information & FAQs

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MeRITS PMO

What is the EDMS?

The Electronic Document Management System (EDMS), branded **FRED** for FDA Regulated Electronic Documents System, is focused on the reduction, and possibly the elimination, of paper-based systems for regulatory data, documents, and records.

This regulated data includes standing operating procedures (SOPs), policies, guidelines, investigational new drugs files (INDs), protocols, clinical study documentation, study reports, FDA correspondence, and much more. FRED end users will be able to browse and navigate regulatory content, search for and retrieve information, as well as read, review, print, and/or download the most current versions of documents. In addition, end users, with appropriate permissions, will be able to add new versions and produce audit reports for each document.

Most importantly, the FRED system enables the Command to streamline processes and mitigate risks through the use of a collaborative, secure information environment.

Why is FRED being implemented?

The Food and Drug Administration (FDA) has regulations and requirements for the information produced by USAMRMC and the systems used to manage that information. One of these requirements,

the Title 21 Code of Federal Regulations (CFR), Part 11, can be thought of as an “umbrella” that covers the computer systems, data, and signature requirements of the Good Laboratory Practices (GLPs) and Good Clinical Practices (GCPs), when the data and signatures are in electronic form. The GLP, GCP, and Good Manufacturing Practice (GMP) regulations, and other FDA regulations that provide the systems, records, and signature requirements, are called “Predicate Rules.” Overall, the FDA expects USAMRMC to provide trustworthy data; accurate and complete records and reports; reliable systems and processes; secure data, systems and facilities; as well as qualified and trained personnel when utilizing computerized records. This compliance is required when FDA-regulated records are created, modified, maintained, archived, retrieved, or transmitted in electronic form, or are electronically signed or submitted to the FDA. The FRED System provides the Command with a means to satisfy the FDA’s electronic records and signature requirements.

FRED Benefits

The FRED System provides the Command with the following benefits:

- Control of electronic information throughout the entire life cycle, from creation to eventual archiving;
- Document integrity through version control;
- A central, secure location for controlled access to regulated documents;
- A collaborative platform for controlled access to regulated documents; and
- Satisfy the FDA’s electronic records and signature requirements – the Title 21 Code of Federal Regulations (CFR), Part 11, and the associated predicate rules.

Who will be utilizing FRED?

Any individual involved in an FDA-regulated process that produces regulatory information (records) or documents intended for any FDA-regulated activity. Examples of these documents include:

- Data and documents required by FDA regulations, such as clinical study reports, patient record datasets, Investigational New Drugs (INDs), investigator brochures, and annual reports;
- Records of the development, use, or maintenance of information systems that are required to support a regulated project (e.g. clinical trial); and,
- Data and documents that are submitted to the FDA for their use in regulatory decision-making.

These individuals are located anywhere regulated activities are conducted where the Army Office of the Surgeon General (OTSG) is the application holder with the FDA.

How can I obtain a FRED Account?

To obtain an account on FRED, end users must first complete the USAMRMC, MeRITS Regulatory Information Systems Course 100 Series Training Program. This Training Program provides basic regulatory information systems instruction as it pertains to the FDA-regulated activities performed at the Command everyday. It is a prerequisite for access to any MeRITS PMO regulated